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THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICA

INVENTION:

: Jackowski et al.

: APOLIPOPROTEIN BIOPOLYMER MARKERS PECEIVED

TECH CENTER 1600/2900 PREDICTIVE OF ALZHEIMERS DISEASE

SERIAL NUMBER

: 10/020,008

FILING DATE

: December 13, 2001

EXAMINER:

: (not assigned yet)

GROUP ART UNIT

: 1645

ATTORNEY DOCKET NO.

: 2132.089

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

CERTIFICATE UNDER 37 CFR 1.8(a)

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Sir:

Pursuant to the Duty to Disclose under 37 C.F.R. §1.56, the references cited on the accompanying form PTO-1449 are hereby brought to the attention of the Examiner for independent evaluation. A copy of each reference is enclosed.

In accordance with 37 C.F.R. §1.97(e), Applicants hereby certify that each item of information contained in the accompanying Supplemental Information Disclosure Statement filed concurrently herewith was cited in a communication from a foreign patent office, namely an International Search Report for a counterpart European patent application, not more than three months prior to the filing of the accompanying Supplemental Information Disclosure Statement. A copy of the International Search Report is also enclosed, which satisfies the requirement for a concise statement of relevancy pursuant to M.P.E.P. §609 (1995).

Applicants submit that the present invention is patentable over these references.

Accordingly, pursuant to 37 C.F.R. §1.97(e), Applicants request consideration and entry of the Supplemental Information Disclosure Statement.

Date: $\frac{9/23/2003}{}$

Bv.

By: ____

Ferris H. Lander

Registration No. 43,377

Respectfully submitted,

McHale & Slavin, P.A.

2855 PGA Boulevard

Palm Beach Gardens, FL 33410

Telephone: (561) 625-6575 Facsimile: (561) 625-6572

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Complete if Known				
Application Number	10/020,008	•		
Filing Date	12/13/2001	00		
First Named Inventor	George Jackowski	, 7		
Art Unit	1645	20		
Examiner Name				
Attorney Docket Number	2132.089			

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Examiner Initials*	Cite No. ¹	Document Number Number-Kind Code ^{2 (# known)}	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, When Relevant Passages or Relevant Figures Appear
		US- E 750 046	06/02/4000	A Opportunity	35.55.4
		^{US-} 5,759,816	06/02/1998	A. Oppenheim	
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	Country Code ³ Number ⁴ Kind Code ⁵ (if known)	MM-DD-YYYY		Or Relevant Figures Appear	T ⁶
	WO99/31227	06/24/1999	Univ Western Ontario		
	WO01/75454	10/11/2001	Oxford Glycosciences		
	WO01/63294	08/30/2001	Oxford Glycosciences		
	WO02/059604	08/01/2002	Oxford Glycosciences		
	WO02/088750	11/07/2002	Oxford Glycosciences		
	WO93/15198	08/05/1993	Rhone-Poulenc Rorer		

Examiner Signature	Date Considered	

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DOCUMENTS			
Name of Patentee Applicant of Cited Doc		Pages, Columns, Lines, Where Relevant Passages or Relevant	1

Examiner	Cite	Document Number	U. S. PATENT D Publication Date	Name of Patentee or	Pogos Calumna Line Mhass
Initials*	Cite No. ¹	Document Number	MM-DD-YYYY	Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
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	Country Code ³ Number ⁴ Kind Code ⁵ (if known)	MM-DD-YYYY		Or Relevant Figures Appear	T ⁶
	WO01/77124	10/18/2001	Genaissance Pharm.		
	WO01/75177	10/11/2001	Government of USA		
			as represented by		
			The Secretary, Dept		
			Health & Human Serv.		
_	No. ¹	Country Code ³ Number ⁴ Kind Code ⁵ (if known) WO01/77124	Country Code ³ Number ⁴ Kind Code ⁵ (<i>if known</i>) MM-DD-YYYY 10/18/2001	Country Code ³ Number ⁴ Kind Code ⁵ (# known) WO01/77124 10/18/2001 Genaissance Pharm. WO01/75177 10/11/2001 Government of USA as represented by The Secretary, Dept	No. 1 Country Code ³ "Number ⁴ " Kind Code ⁵ (# known) WO01/77124 Date MM-DD-YYYY 10/18/2001 Genaissance Pharm. WO01/75177 10/11/2001 Government of USA as represented by The Secretary, Dept

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Application Number	10/020,008	
Filing Date	12/13/2001	
First Named Inventor	George Jackowski	\
Art Unit	1645	Ec. Cr
Examiner Name		Ca
Attorney Docket Number	2132.089	1/2

		NON PATENT LITERATURE DOCUMENTS	- Of
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
		J. SILKENSEN et al, "Identification of clusterin sequences mediating renal tubular cell interactions", J. Peptide Res., 54(5):449-457 (November, 1999)	
		A. CSASZAR et al, "Association of the apolipoprotein A-IV codon 360 mutation in patients with Alzheimer's disease", Neuroscience Letters, 230(3):151-154 (1997)	
		S. HARR et al, "Brain Expression of Apolipoproteins E, J, and A-I in Alzheimer's Disease", J. Neurochem., 66(6):2429-2435 (1996)	
		B. VERGES et al, "Macrovascular disease is associated with increased plasma apolipoprotein A-IV levels in NIDDM", Diabetes, 46(1):125-132 (January, 1997)	
		P. WONG et al, "Molecular characterization of human TRPM-2/clusterin, a gene associated with sperm maturation, apoptosis and neurodegeneration", Eur. J. Biochem., 221(3):917-925 (1994)	
		N. DEMEESTER et al, "Characterization and functional studies of lipoproteins, lipid transfer proteins, and lecithin:cholesterol acyltransferase in CSF of normal individuals and patients with Alzheimer's disease", J. Lipid Res., 41(6):963-974 (June, 2000)	
		R. STEWART, "Cardiovascular factors in Alzheimer's disease", J. Neurol. Neurosurg. Psychiatry, 65(2):143-147 (1998)	
		J. SLEMMON et al, "Profiling of endogenous peptides as a tool for studying development and neurological disease", Biopolymers, 43(2):157-170 (1997)	

Examiner	Date	
Signature	Considered	

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